This Page Is Inserted by IFW Operations and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

As rescanning documents will not correct images, please do not report the images to the Image Problem Mailbox.

REMARKS

Summary of Office Action

Claims 28-40 are pending in the above-identified patent application.

The Examiner withdrew objections to claim 28, 33 and 35 and rejections under 35 U.S.C. § 112, 2^{nd} para. of claims 28-38.

The Examiner rejected claims 28-35 and 37-40 under 35 U.S.C. § 103(a) as being unpatentable over Lesh et al. U.S. Patent No. 6,152,144 (hereinafter, "Lesh") in view of Stevens et al. U.S. Patent No. 5,797,960 (hereinafter, "Stevens").

Summary of Applicants' Reply

Applicants have amended claims 28, 34 and 35, have added claim 41 and respectfully traverse the Examiner's rejections. Claims 34-35 have been amended to more particularly point out and distinctly claim subject matter of applicants' invention. The amendment of claim 28 and the addition of claim 41 are discussed below. No new matter was introduced by the amendments or the claim addition.

Applicants respectfully request acknowledgment of consideration of a reference cited in a March 27, 2003

Supplemental Information Disclosure Statement (copies of

Supplemental Information Disclosure Statement, Form PTO-1449 and Return Postcard attached).

Applicants' Reply to the Rejections Under 35 U.S.C. § 103

Claims 28-35 and 37-40 were rejected under

35 U.S.C. § 103(a) as being unpatentable over Lesh in view of

Stevens. Claim 28 is independent and claims 29-35 and 37-40

depend directly or indirectly from claim 28. The rejections

are respectfully traversed.

Amended claim 28 is directed to a method for implanting a device in an atrial appendage and requires, in part, the provision of a tube assembly comprising:

- (1) an outer tube;
- (2) a shaft for urging the device through the assembly; and
- (3) a positioning guide for engaging at least a portion of an atrial wall for mechanical support of portions of the tube assembly.

The claim also requires, in part:

(1) percutaneously advancing the tube assembly through a blood vessel to establish a passageway to an atrium;

- (2) introducing the positioning guide to a location near an ostium of the atrial appendage;
- (3) deploying the positioning guide to engage the portion of an atrial wall for mechanical support; and
- (4) using the shaft to urge the device through the passageway to a position within the atrial appendage.

In a June 5, 2003 Office Action (at p. 4-6), the Examiner rejected claim 28 under 35 U.S.C. § 102 over Lesh and under 35 U.S.C § 103 over Lesh in view of Stevens. Examiner cited a first Lesh embodiment (hereinafter, "Lesh A") shown in FIGS. 20-23 and a second Lesh embodiment (hereinafter, "Lesh B") shown in FIGS. 13-14 and 16. Amendment and Reply to Office Action dated September 24, 2003, applicants traversed the rejection by amending claim 28 to recite features of a securement means attached to the outer tube. Applicants have herein canceled the securement means features in claim 28 and presented new claim 41 that depends from claim 28 and recites the securement means features. Neither the amendment nor the new claim introduces new matter. Applicants also respectfully assert for the following reasons that amended claim 28, which does not require securement means, and new claim 41, which includes

securement means features, are not, as alleged in the June 5, 2003 Office Action, anticipated by Lesh or obvious from Lesh in view of Stevens.

Regarding Lesh A, applicants respectfully note that claim 28 recites a method for implanting a device in an atrial appendage. FIGS. 20-23 show Lesh A and a sequence of steps performed using Lesh A. FIG. 23 shows the final state of a left atrial appendage after the steps are performed. The left atrial appendage in the final state is empty. Lesh element 173 is shown crimping wall tissue 172 against Lesh tissue attachment members 158 (shown in FIGS. 20-22). Applicants respectfully assert that Lesh A is not a device for implanting anything in an atrial appendage.

Regarding Lesh B, applicants respectfully submit that catheter 111 is not an outer tube, as alleged by the Examiner. Lesh FIG. 14 shows "inner shaft 121[,]" but shows that inner shaft 121 is an "inner" shaft with respect to inflatable member 114, not with respect to catheter 111.

Applicants respectfully submit that, therefore, catheter 111 is not an outer tube, as required by claim 28. Applicants respectfully submit also that inner shaft 121 internally supports inflatable member 114 (Lesh at col. 11, ln. 31-34,

FIGS. 13-14), but cannot be used to urge inflatable member 114, as required by claim 28.

Applicants respectfully submit further that Lesh B does not show a positioning guide. The Examiner alleged that Lesh inflatable member 114 is a positioning guide.

Applicants respectfully submit that Lesh (FIG. 16 and col. 12, ln. 11-13, e.g.) teaches that member 114 is a device that is deployed in a left atrial appendage, not a device for mechanically supporting a tube assembly, as required by claim 28. Furthermore, inflatable member 114 engages left atrial appendage wall tissue 135 and not atrial wall tissue, as required by claim 28.

Applicants respectfully submit, therefore, that none of Lesh A, Lesh B and any other teaching of Lesh shows or suggests all of the features required by claim 28.

Applicants respectfully submit further that claims 28-35 and 37-41 are not obvious from Lesh in view of Stevens, because Stevens does not make up for the shortcomings of Lesh set forth above. Applicants respectfully submit, therefore, that claims 28-35 and 37-41 are patentable.

Conclusion

For at least the reasons set forth above, applicants respectfully submit that claims 28-35 and 37-41 are patentable and respectfully request that the December 30, 2003 rejection under 35 U.S.C. § 103(a) and the June 5, 2003 rejections under 35 U.S.C. §§ 102(e) and 103(a) be withdrawn. Applicants respectfully submit that this application is in condition for allowance. Reconsideration and prompt allowance of this application are respectfully requested.

Respectfully submitted,

Edward M. Arons (Reg. No. 44,511

Agent for applicants

FISH & NEAVE

Customer No. 1473

1251 Avenue of the Americas New York, New York 10020-1105

Tel.: (212) 596-9000

Fax: (212) 596-9000

Attachments